## **REMARKS**

Claims 1-9 and 12-14, as amended, appear in this application for the Examiner's review and consideration. Claim 1 was amended to recite that the chamber comprises a beneficial agent and is supported by the specification and originally filed claims. As no new matter has been added by these claim amendments, their entry at this time is warranted.

Claims 1-4, 8-9 and 12 were rejected under 35 U.S.C. 102(b) as being anticipated by DE 3920775A1 to Fresenius AG for the reasons stated on page 2 of the office action. Applicant respectfully traverses this rejection.

Applicant notes that the present invention is directed to an apparatus for modifying and feeding a liquid nutritional feeding composition. The apparatus comprises a chamber comprising at least one beneficial agent for modifying a liquid nutritional feeding composition, the chamber has an inlet connectable to a container that contains the nutritional feeding composition, an outlet connectable to a feeding means, and pumping means, which is adapted for pumping the nutritional feeding composition from the container into the chamber and back to the container for mixing the beneficial agent into the nutritional feeding composition.

The cited reference, in contrast, consists of two chambers, which must be joined to prepare a solution. The mixture is effected by using both chambers as pressing means.

Specifically, after the two bags are joined, the lower chamber is pressed to raise the level of the carrier until the upper chamber containing the active ingredients is filled with the carrier. After the mixture is effected in the upper chamber, the chamber is pressed to move the mixture to the lower chamber. The solution is then released from the lower chamber via an outlet.

The cited reference does not show one chamber with pumping means capable of drawing a feeding composition located from a container into a chamber containing a beneficial agent and

moving the resulting mixture back to the container. Instead, the cited reference requires pressing both chambers to effectuate preparation of a solution. Accordingly, the cited reference does not disclose each and every element of the present invention and therefore, claims 1-4, 8-9, and 12 are not anticipated by DE 3920775 A1. Applicant respectfully requests that the Examiner withdraw the rejection to those claims under 35 U.S.C. § 102(b).

Claims 5-7 and 13-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over DE 3920775 A1 for the reasons stated on page 2 of the Office Action. Applicant respectfully traverses.

Obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found in the reference. *M.P.E.P.* 2143.01 (7th ed. Rev 1 2000). As pointed out above, the cited reference fails to teach or suggest a pumping means adapted for pumping the nutritional feeding composition from the container into the chamber and back to the container. Instead, the cited reference requires joining two chambers together and pressing both chambers so that mixing of the carrier solution and active ingredients can occur. The cited reference does not teach or suggest a pumping means adapted for pumping the feeding solution from the container to the chamber, which comprises at least one beneficial agent and then back to the container for release via the outlet. Additionally, the cited reference does not teach or suggest two chambers that remain separate and do not require enjoinment for mixing of the ingredients. Thus, the structure of the apparatus of the present invention and that of the cited reference are distinguishable.

Accordingly, the present invention is not obvious over DE 3920775 A1. Thus, Applicant respectfully requests that the Examiner withdraw the rejection of claims 5-7 and 13-14 under 35 U.S.C. 103(a).

No fee is believed to be due for this submission. Should any fees be due, however, please charge such fees to Winston & Strawn Deposit Account No. 501-814.

A change of address for applicants' attorney is enclosed. Please direct all future communications to Customer Number 28765.

Date: 5/7/01

Respectfully submitted,

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Enclosures

## **APPENDIX A---MARKED UP VERSION**

## **IN THE CLAIMS**

1. (Amended) An apparatus for modifying and feeding a liquid nutritional feeding composition comprising:

a chamber [for receiving] <u>comprising</u> at least one beneficial agent for modifying a liquid nutritional feeding composition, the chamber having an inlet connectable to a container that contains the nutritional feeding composition and an outlet connectable to a feeding means, and

a pumping means associated with the chamber <u>wherein said pumping means is adapted</u> for pumping the nutritional feeding composition from the container into the chamber and back into the container to mix the beneficial agent and the nutritional feeding composition.

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## APPENDIX B--PENDING CLAIMS

1. An apparatus for modifying and feeding a liquid nutritional feeding composition comprising:

a chamber comprising at least one beneficial agent for modifying a liquid nutritional feeding composition, the chamber having an inlet connectable to a container that contains the nutritional feeding composition and an outlet connectable to a feeding means, and

a pumping means associated with the chamber wherein said pumping means is adapted for pumping the nutritional feeding composition from the container into the chamber and back into the container to mix the beneficial agent and the nutritional feeding composition.

- 2. An apparatus according to claim 1, wherein the pumping means comprises varying the volume of the chamber.
- 3. An apparatus according to claim 2, wherein the chamber comprises at least one flexible wall capable of being squeezed and released for pumping of the nutritional feeding composition.
- 4. An apparatus according to claim1, wherein the chamber comprises at least one beneficial agent selected from the group consisting of nutrients, probiotics, medicaments, diagnostic agents, and mixtures thereof.
- 5. An apparatus according to claim 1, wherein at least one beneficial agent is dispersible in the nutritional feeding composition in less than 1 min.

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- 6. An apparatus according to claim 1, wherein at least one beneficial agent is dispersible in the nutritional feeding composition in less than 30 sec.
- 7. An apparatus according to claim 4, wherein the volume of beneficial agent constitutes from 30% to 50% of the volume of the chamber.
- 8. An apparatus according to claim 1, wherein the inlet is provided with a hollow spike for piercing a port on the container to create a fluid path for the nutritional feeding composition.
- 9. An apparatus according to claim 1, wherein the feeding means comprises a hollow spike for piercing the outlet of the chamber to create a fluid path for the nutritional feeding composition with the beneficial agent.
- A method for modifying and feeding a liquid nutritional feeding composition comprising: connecting a chamber according to claim 1 to a container comprising a liquid nutritional feeding composition,

pumping liquid feeding composition into the chamber and liquid nutritional feeding composition and beneficial agent back to the container to mix the nutritional feeding composition with the beneficial agent,

connecting the feeding means to the outlet of the chamber, and allowing the modified nutritional feeding composition to flow through the chamber into the feeding means.

- 13. The method of claim 12 wherein the feeding involves enterally supplying the liquid nutritional feeding composition.
- 14. The method of claim 12 wherein the feeding involves intravenously supplying the liquid nutritional feeding composition.